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CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
LOS ANGELESBY 

Phillip E. Benson, CA Bar #97420
 WARREN ■ BENSON Law Group
 620 Newport Center Dr., Ste 1100
 Newport Beach, CA 92660
 Tel: 949-721-6636; Fax: 952-955-5177
philbenson@warrenbensonlaw.com

Donald R. Warren, CA Bar #138933
 WARREN ■ BENSON Law Group
 7825 Fay Ave, Ste 200
 La Jolla, CA 92037
 Tel: 858-456-1900; Fax: 858-454-5878
donwarren@warrenbensonlaw.com

David B. Ketrosier, M.D., MN Bar # 0298803
 P.O. Box 427
 Hopkins, MN 55343
 Tel: 612-384-3286; Fax: 952-681-3286
bakquak@comcast.net

Attorneys for *Qui Tam* Plaintiffs
 Doris Modglin and Russ Milko

UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,
ex rel. Doris Modglin and Russ Milko,

Plaintiffs,

vs.

DJO GLOBAL INC., DJO LLC, DJO
 FINANCE LLC, ORTHOFIX, INC.,
 BIOMET, INC., and EBI, LP,

Defendants.

Case **CV12-7152**

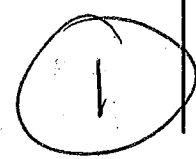
COMPLAINT

DEMAND FOR JURY TRIAL

[FILED IN CAMERA AND UNDER
 SEAL PURSUANT TO 31 U.S.C. §
 3730(b)(2)]

BY FAX

COMPLAINT



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 Newport Beach, CA 92660
 Tel: 949-721-6636; Fax: 952-955-5177
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COMPLAINT

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1 entities defendant DJO, LLC, (Cal. foreign corp. # 199916310078) and defendant DJO Finance
2 LLC (Cal. foreign corp. # C3478665), jointly referred to as "DJO", manufacture and market
3 throughout the United States non-invasive orthopedic medical devices (which are included
4 within the definition of durable medical equipment or "DME"), including the CMF SpinaLogic, a
5 bone growth stimulator indicated as an adjunct electromagnetic treatment to lumbar spinal fusion
6 surgery. The for profit DGO entities are Delaware corporations headquartered at 1430 Decision
7 Street, Vista, California. DJO is an approved Medicare direct-billing DME provider under
8 provider numbers 1283420001 and 1497731533 and possibly others.

9 6. Defendant Orthofix, Inc., (Cal. foreign corp. #C1950206) is a Minnesota
10 Corporation headquartered at 3451 Plano Parkway, Lewisville, TX 75056. Orthofix is a for profit
11 medical device (DME) company which manufactures and markets throughout the United States
12 non-invasive bone growth stimulators, including the Spinal-Stim which is indicated as an adjunct
13 electromagnetic treatment to primary lumbar spinal fusion surgery and the Cervical-Stim which
14 is indicated as an adjunct electromagnetic treatment to cervical spine fusion surgery. Orthofix is
15 an approved Medicare direct-billing DME provider under provider number XX1235136060 and
16 possibly others.

17 7. Defendant Biomet, Inc., (Cal. foreign corp. # C3318611) and its related entity
18 defendant EBI, LP, jointly referred to as "Biomet", is a for profit Indiana Corporation which lists
19 its headquarters at 56 E. Bell Dr., Warsaw, Indiana. Biomet is a medical device (DME) company
20 which manufactures and markets throughout the United States non-invasive bone growth
21 stimulators, including the SpinalPak which is indicated as an adjunct to lumbar spinal surgery.

22 8. At all times relevant hereto, defendants acted through their agents and employees
23 and the acts of defendants' agents and employees were within the scope of such agency and
24 employment.

25
26 **IV.**

27 **REGULATORY AND FACTUAL BACKGROUND**

28 **COMPLAINT**

1
2 9. Despite industry attempts to downgrade the categorization of non-invasive bone
3 growth stimulators from Class III to Class II, non-invasive bone growth stimulators have been
4 historically categorized by the United States Food and Drug Administration (FDA) as Class III
5 devices under FDA product code LOF and may only be marketed in the United States if they
6 have received pre-market approval (PMA) from the FDA. See 72 FR 1951.

7 10. To obtain PMA, applicants are required to submit an application to the FDA
8 detailing: 1) extensive safety testing data; 2) the contents and operation of the device; 3) a
9 description of methods used to manufacture, process, package and install the device; 4) samples
10 of the device; 5) proposed labeling for the device; and 6) all other information required under the
11 federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360e(c)(1). Because Class III devices are
12 considered to present a potential unreasonable risk of illness or injury, they receive the strictest
13 FDA regulation. Once approved, a device may not be manufactured, packaged, stored, labeled,
14 distributed, or advertised in a manner that is inconsistent with any conditions of approval
15 specified in the PMA approval order for the device. 21 C.F.R. § 814.80.

16 11. Medicare, TriCare, Medicaid and other federally sponsored health care programs
17 do not cover payment for Class III devices unless they have obtained pre-market approval from
18 the FDA or received an investigational device exemption (IDE) from the FDA. See Medicare
19 Benefit Policy Manual, Chapter 14 - Medical devices. None of the false claims for payment
20 alleged in this case are believed to involve bone growth stimulators charged to the federal
21 programs under any then existing IDE.

22 12. Medicare coverage for electrical stimulation for fracture healing has been in effect
23 since 1980. Initial coverage was limited to non-invasive devices for the treatment of nonunion of
24 bone fractures, failed fusion, and congenital pseudoarthroses. In 1996, Medicare first approved
25 reimbursement for the limited use of noninvasive bone growth stimulators adjunct to spinal
26 fusion surgery, subject to FDA pre-market approval. See Medicare National Coverage
27 Determinations Manual, Ch. 1, Part 2, section 150-2.

28
COMPLAINT

1 13. DJO's CMF SpinaLogic (aka SpinaLogic 1000) has received FDA pre-market
2 approval (PMA) for lumbar use and no other. The FDA's PMA for the SpinaLogic, the only non-
3 invasive spinal bone growth stimulator manufactured and distributed by DJO, specifically states
4 that DJO's device "is indicated as an adjunct electrical treatment to primary lumbar spinal fusion
5 surgery." Any distribution of DJO's CMF SpinaLogic for use inconsistent with the PMA
6 condition limiting it to only lumbar use is outside the scope of the PMA and any such use is not
7 covered for reimbursement by Medicare, Medicaid, Tricare and other federally sponsored health
8 care programs.

9 14. Biomet's SpinalPak has received FDA pre-market approval (PMA) for lumbar use
10 and no other. The FDA's PMA for the SpinalPak, the only non-invasive spinal bone growth
11 stimulator manufactured and distributed by Biomet, specifically states that Biomet's device "is
12 indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery."

13 15. In August 2003, Orthofix entered into a settlement agreement with the United
14 States Government to pay back \$1.7 million for charging Tricare for the use of its spinal bone
15 growth stimulator for cervical use when it had, up to that time, received pre-market approval only
16 for lumbar use. Even though Orthofix's lumbar devices had been prescribed by some physicians
17 for cervical use, Tricare coverage policies, as well as Medicare and other government sponsored
18 health care programs, do not pay for Class III devices that are distributed and used outside the
19 scope of their PMA. In January 2005, Orthofix finally obtained PMA for its Cervical-Stim spinal
20 bone growth stimulator which is specifically indicated as an adjunct to cervical fusion surgery in
21 patients at high risk for non-fusion.

22 16. As DME providers, the defendants bill Medicare Part B and the other
23 federally sponsored health care programs directly using CMS Claim Form 1500, accompanied by
24 a Certificate of Medical Necessity, DME 04.04C (CMS-847), which is specific to Class III
25 osteogenesis stimulators. In Section C of the CMS 847 form, the DME provider is required to
26 provide a narrative description of the device and its "Medicare Fee Schedule Allowance." Since
27 there is only one issued higher level HCPCS code available for use on both CMS forms for non-
28

COMPLAINT

1 invasive spinal application osteogenesis stimulators (E0748) (no lower level HCPCS code or
 2 modifier specific to lumbar or cervical application has ever been issued), unless the DME
 3 provider specifically indicates in Section C of the CMS-847 form that the device was distributed
 4 for a non-indicated lumbar or cervical use, by submitting the form for reimbursement, the
 5 provider is representing that the bone growth stimulator was distributed and used as indicated
 6 under its PMA and is reimburseable. Additionally, by submitting the CMS Form 1500 for
 7 reimbursement, the DME provider is representing that the bone growth stimulator was
 8 distributed and used within the scope of its PMA indicated use since any other distribution and
 9 use is non-reimburseable.

10
 11 **V.**

12 **CLAIM AGAINST DJO, ORTHOFIX AND BIOMET FOR**
 13 **VIOLATION OF THE FALSE CLAIMS ACT (31 U.S.C. § 3729 (a)(1)(A) & (B))**
 14

15 17. Plaintiffs incorporate by reference herein the allegations made above in
 16 paragraphs 1-16, inclusive.

17 18. Following its settlement with Tricare in 2003 and until the receipt of its
 18 PMA in January 2005 for the cervical use of its Cervical-Stim device, with the exception of
 19 Tricare, defendant Orthofix continued to submit claims for payment to Medicare, Medicaid and
 20 other federally sponsored health insurance programs for Class III bone growth stimulators
 21 approved for lumbar use only that were actually distributed and used for cervical spinal use. In
 22 the year preceding its settlement with Tricare in 2003 (and excluding Tricare for purposes of this
 23 complaint), defendant Orthofix submitted claims for payment to Medicare, Medicaid and other
 24 federally sponsored health insurance programs for Class III bone growth stimulators approved for
 25 lumbar use only that were actually distributed and used for cervical spinal use.

26 19. Over the course of the last ten years, defendants DJO and Biomet have routinely
 27 submitted claims for payment to Medicare, Medicaid, Tricare and other federally sponsored
 28

COMPLAINT

1 B. For any and all other relief to which the plaintiffs may be entitled.
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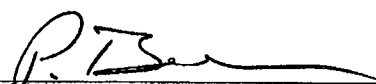
3 **JURY DEMAND**

4 Plaintiffs request trial by jury.
5

6
7 Dated: August 20, 2012

Respectfully Submitted,

9 **WARREN ■ BENSON Law Group**
10

11
12 By: 
13 Phillip E. Benson
14 Attorneys for *Qui Tam* Plaintiffs
Doris Modglin and Russ Milko
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COMPLAINT

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEETI (a) PLAINTIFFS (Check box if you are representing yourself ☐)
United States ex rel. Doris Modglin and Russ MilkoDEFENDANTS
DJO Global, Inc.; DJO LLC; DJO Finance LLC; Orthofix, Inc.; Biomet, Inc.; and
EBI, LP

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)

Warren-Benson Law Group, 620 Newport Center Dr., Ste 1100, Newport Beach, CA 92660; 949-721-6636

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☒ 1 U.S. Government Plaintiff ☐ 3 Federal Question (U.S. Government Not a Party)☐ 2 U.S. Government Defendant ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant.)

Citizen of This State

PTF DEF

☐ 1 ☐ 1

Incorporated or Principal Place of Business in this State

PTF DEF

☐ 4 ☐ 4

Citizen of Another State

☐ 2 ☐ 2

Incorporated and Principal Place of Business in Another State

☐ 5 ☐ 5

Citizen or Subject of a Foreign Country

☐ 3 ☐ 3

Foreign Nation

☐ 6 ☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1 Original Proceeding☐ 2 Removed from State Court☐ 3 Remanded from Appellate Court☐ 4 Reinstated or Reopened☐ 5 Transferred from another district (specify):☐ 6 Multi-District Litigation☐ 7 Appeal to District Judge from Magistrate JudgeV. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check 'Yes' only if demanded in complaint.)CLASS ACTION under F.R.C.P. 23: ☐ Yes ☒ No☒ MONEY DEMANDED IN COMPLAINT: \$ TBDVI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
31 U.S.C. § 3730(b)(2)

VII. NATURE OF SUIT (Place an X in one box only.)

- | | | | | | |
|--|--|---|--|--|---|
| <input type="checkbox"/> 400 State Reapportionment | <input type="checkbox"/> 110 Insurance | <input type="checkbox"/> 310 Airplane | <input type="checkbox"/> 370 Other Fraud | <input type="checkbox"/> 510 Motions to Vacate Sentence | <input type="checkbox"/> 710 Fair Labor Standards Act |
| <input type="checkbox"/> 410 Antitrust | <input type="checkbox"/> 120 Marine | <input type="checkbox"/> 315 Airplane Product Liability | <input type="checkbox"/> 371 Truth in Lending | <input type="checkbox"/> 530 General | <input type="checkbox"/> 720 Labor/Mgmt. Relations |
| <input type="checkbox"/> 430 Banks and Banking | <input type="checkbox"/> 130 Miller Act | <input type="checkbox"/> 320 Assault, Libel & Slander | <input type="checkbox"/> 380 Other Personal Property Damage | <input type="checkbox"/> 535 Death Penalty | <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act |
| <input type="checkbox"/> 450 Commerce/ICC Rates/etc. | <input type="checkbox"/> 140 Negotiable Instrument | <input type="checkbox"/> 330 Fed. Employers' Liability | <input type="checkbox"/> 385 Property Damage Product Liability | <input type="checkbox"/> 540 Mandamus/Other | <input type="checkbox"/> 740 Railway Labor Act |
| <input type="checkbox"/> 460 Deportation | <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment | <input type="checkbox"/> 340 Marine | <input type="checkbox"/> 422 Appeal 28 USC 158 | <input type="checkbox"/> 550 Civil Rights | <input type="checkbox"/> 790 Other Labor Litigation |
| <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations | <input type="checkbox"/> 151 Medicare Act | <input type="checkbox"/> 345 Marine Product Liability | <input type="checkbox"/> 423 Withdrawal 28 USC 157 | <input type="checkbox"/> 555 Prison Condition | <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act |
| <input type="checkbox"/> 480 Consumer Credit | <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Veterans) | <input type="checkbox"/> 350 Motor Vehicle | <input type="checkbox"/> 441 Voting | <input type="checkbox"/> 610 Agriculture | <input type="checkbox"/> 820 Copyrights |
| <input type="checkbox"/> 490 Cable/Sat TV | <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits | <input type="checkbox"/> 355 Motor Vehicle Product Liability | <input type="checkbox"/> 442 Employment | <input type="checkbox"/> 620 Other Food & Drug | <input type="checkbox"/> 830 Patent |
| <input type="checkbox"/> 810 Selective Service | <input type="checkbox"/> 160 Stockholders' Suits | <input type="checkbox"/> 360 Other Personal Injury | <input type="checkbox"/> 443 Housing/Accommodations | <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 | <input type="checkbox"/> 840 Trademark |
| <input type="checkbox"/> 850 Securities/Commodities/Exchange | <input type="checkbox"/> 190 Other Contract | <input type="checkbox"/> 362 Personal Injury-Med Malpractice | <input type="checkbox"/> 444 Welfare | <input type="checkbox"/> 630 Liquor Laws | <input type="checkbox"/> 861 HIA (1395ff) |
| <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 | <input type="checkbox"/> 195 Contract Product Liability | <input type="checkbox"/> 365 Personal Injury-Product Liability | <input type="checkbox"/> 445 American with Disabilities - Employment | <input type="checkbox"/> 640 R.R. & Truck | <input type="checkbox"/> 862 Black Lung (923) |
| <input checked="" type="checkbox"/> 890 Other Statutory Actions | <input type="checkbox"/> 196 Franchise | <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability | <input type="checkbox"/> 446 American with Disabilities - Other | <input type="checkbox"/> 650 Airline Regs | <input type="checkbox"/> 863 DIWC/DIWW (405(g)) |
| <input type="checkbox"/> 891 Agricultural Act | <input type="checkbox"/> 210 Land Condemnation | <input type="checkbox"/> 462 Naturalization Application | <input type="checkbox"/> 440 Other Civil Rights | <input type="checkbox"/> 660 Occupational Safety/Health | <input type="checkbox"/> 864 SSID Title XVI |
| <input type="checkbox"/> 892 Economic Stabilization Act | <input type="checkbox"/> 220 Foreclosure | <input type="checkbox"/> 463 Habeas Corpus-Alien Detainee | | <input type="checkbox"/> 690 Other | <input type="checkbox"/> 865 RSI (405(g)) |
| <input type="checkbox"/> 893 Environmental Matters | <input type="checkbox"/> 230 Rent Lease & Ejectment | <input type="checkbox"/> 465 Other Immigration Actions | | | <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) |
| <input type="checkbox"/> 894 Energy Allocation Act | <input type="checkbox"/> 240 Torts to Land | | | | <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609 |
| <input type="checkbox"/> 895 Freedom of Info. Act | <input type="checkbox"/> 245 Tort Product Liability | | | | |
| <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice | <input type="checkbox"/> 290 All Other Real Property | | | | |
| <input type="checkbox"/> 950 Constitutionality of State Statutes | | | | | |

FOR OFFICE USE ONLY: Case Number:

CV12-7152

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET**

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☒ No ☐ Yes

If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☒ No ☐ Yes

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or

☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or

☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or

☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.

☒ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.

☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	San Diego County; Texas; Indiana

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.

Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties	All California Counties and States

* Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties

Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): P. J. S.

Date 8/20/12

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge Margaret M. Morrow and the assigned discovery Magistrate Judge is Jay C. Gandhi.

The case number on all documents filed with the Court should read as follows:

CV12- 7152 MMM (JCGx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

=====

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

☒ **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

☐ **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

☐ **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.